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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,883	06/22/2006	Stefan Golz	SMSD-0068/2004P56027 WOUS	5304
28524	7590	11/23/2011	EXAMINER	
SIEMENS CORPORATION INTELLECTUAL PROPERTY DEPARTMENT 170 WOOD AVENUE SOUTH ISELIN, NJ 08830			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	
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			11/23/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,883	Applicant(s) GOLZ ET AL.	
	Examiner RUIXIANG LI	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 18 and 27-31 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 18 and 27-31 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicant's submission filed on 11/08/2011 has been entered. Claims 18 and 27-31 are pending and under consideration.

Withdrawn Objections and/or Rejections

The rejection of claim 18 under 35 U.S.C. 112, first paragraph, is withdrawn in view of amended claim.

The rejection of claim 18 under 35 U.S.C. 112, second paragraph is withdrawn in view of amended claim.

The objection to claim 18 is withdrawn in view of amended claim.

Claim Rejections under 35 USC § 112, 1st paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 18 and 27-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and use the invention.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Amended claim 18 is now drawn to a method of diagnosing stomach tumor in a test mammal comprising determining the amount of AdipoR1 polynucleotide comprising SEQ ID NO: 5 in a sample of a test mammal. Claim 29 recites a limitation, "wherein said AdipoR1 polynucleotide comprises nucleotides 299 to 376 of SEQ ID NO: 1", whereas claim 30 recites a limitation, "wherein said AdipoR1 polynucleotide encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 2". The claims are overly broad because they encompass a method of diagnosing stomach tumor comprising determining not only the nucleic acid sequence of SEQ ID NO: 1 but also a variant or a fragment thereof.

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The sequence search reveals that the AdipoR1 polynucleotide of SEQ ID NO: 1 is known in the prior art (see, e.g., Friedman et al., WO200298898-A2, December 12, 2002). However, there are no teachings in the art that an artisan could potentially diagnose stomach tumor in a mammal by detecting an AdipoR1 polynucleotide of SEQ ID NO: 1 or a variant or a fragment thereof.

The specification discloses asserts that the human AdipoR1 is highly expressed in the tissues of gastroenterological system: stomach, stomach tumor, small intestine, rectum, and the rectum tumor (page 61, last paragraph). The specification discloses that the human AdipoR1 mRNA amount in the tissue of Stomach is about 20-fold higher than the human AdipoR1 mRNA amount in stomach tumor (Example 2; Table 1 on page 103). However, the specification does not provide any statistical data. There is no indication how many samples were analyzed. There are no guidance and/or working examples on how to diagnose stomach tumor in a mammal.

Moreover, the nucleotide sequence set forth in SEQ ID NO: 5 (nucleotides 325 to 348 of SEQ ID NO: 1) was used in the specification as a probe to detect the mRNA amount using RT-PCR. However, the specification does not disclose that detection of a polynucleotide comprising SEQ ID NO: 5 or a polynucleotide comprising nucleotides 299 to 376 of SEQ ID NO: 1 reflects the mRNA level of human AdipoR1. It is unpredictable whether detection of such a short polynucleotide of SEQ ID NO: 5 or nucleotides 299 to 376 of SEQ ID NO: 1 or a variant that comprises such a short

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polynucleotide can be used to diagnose stomach tumor. Furthermore, claim 30 encompasses any human AdipoR1 polynucleotides that encode the amino acid sequence of SEQ ID NO: 2. There is one mRNA existing for the amino acid sequence of SEQ ID NO: 2.

The skill in the area of diagnosing a disease by determining the mRNA level is generally high. However, without knowing a correlation between stomach tumor and the expression level of an AdipoR1 polynucleotide, it is unpredictable whether stomach tumor in a mammal can be diagnosed by determining the amount of AdipoR1 polynucleotides encompassed in the instant claims. It would take undue experimentation for one skilled in the art to make and use the claimed invention.

The courts have stated that patent protection is granted in return for an enabling disclosure. Reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. See *Genetech v. Novo Nordick A/S* (CAFC) 42 USPQ2d 1001 (1997). Similarly, as stated in *Rasmusson v SmithKline Beecham Corp.*, 75 USPQ2d 1297-1303 (CAFC 2005), "if mere plausibility were the test for enablement under section 112, Applicants could obtain patent rights to 'inventions' consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the 'inventor' would be rewarded the spoils instead of the party who demonstrated that the method actually worked. The scenario is not consistent with the statutory requirement that the inventor enable an invention rather

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than merely proposing an unproved hypothesis. In the instant case, the instant disclosure clearly evidences that the specification does not enable the claimed invention.

Accordingly, in view of the above factors, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/

Primary Examiner, Art Unit 1646

November 19, 2011